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EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/552,515	PASTAN ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *12-25,31-38 and 41-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11,26-30,39,40,47 and 48* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/6/05* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Election filed September 11, 2006 in response to the Office Action of July 28, 2006 is acknowledged. Applicant elected with traverse Group I (claims 1-5, 26-30, and 39).

Group II, drawn to polynucleotides that encode the polypeptide of claim 6, is hereby rejoined with Group I for examination purposes because the prior art does not teach the shared special technical feature of the claimed proteins or nucleic acids.

Claims 1-46 are pending. New claims 47 and 48 were added. Claims 12-25, 31-38, 41-46 are withdrawn from further consideration by the examiner under 35 CFR 1.142(b) as being drawn to non-elected inventions. Claims 1-11, 26-30, 39, 40, 47, and 48 are currently under prosecution.

Specification/ Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because Figure 2 fails to show the tissue specific expression of mRNA encoding SV-NGEP as disclosed in the "Brief Description of the Drawings". Two of the figures in Figure 2 appear as solid black graphs. Further, Figure 2 fails to distinguish between 2A and 2B while there appear to be 3 items shown. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the

sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 7 appears to be free of the art but is objected to as being dependent upon a rejected base claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-5, 39 47, and 48 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claims are drawn to an isolated polypeptide comprising: (1) an amino acid sequence at least 90% homologous to SEQ ID NO:1; or (2) at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule; or (3) an amino acid sequence set forth as SEQ ID NO:1 (claim 1), the isolated polypeptide of claim 1 comprising a polypeptide having an amino acid sequence at least 90% homologous to SEQ ID NO:1 (claim 2), the isolated polypeptide of claim 2 comprising an amino acid sequence at least 95% homologous to SEQ ID NO:1 (claim 3), the isolated polypeptide of claim 1 comprising at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule (claim 5), a pharmaceutical composition comprising a therapeutically effective amount of the polypeptide of claim 1 in a pharmaceutically acceptable carrier (claim 39), the isolated polypeptide of claim 1 consisting of at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule (claim 47), a fusion protein comprising (a) the polypeptide of claim 1, wherein the polypeptide consists of at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is at least eight to ten amino acids in length and binds a MHC molecule; and (b) a heterologous polypeptide (claim 48).

The specification discloses a predicted amino acid sequence for an SV-NGEP protein based on the nucleotide sequence of SEQ ID NO:2 (p 51, lines 18-21; Example 3). SEQ ID NO:2, the polynucleotide, was found to be uniquely expressed in prostate

tissue and prostate cancer tissue but not in other normal tissues (Example 2). The specification discloses the prediction of 9-mers of SEQ ID NO:1 that would bind to HLA2-01 (an MHC molecule) (p. 25, lines 12-26). The specification does not provide any working examples with regards to the function or use of the disclosed SV-NGEP protein.

The specification prophetically asserts a specific utility for the claimed polypeptides in methods of producing an antibody for the detection of the claimed polypeptide in order to detect prostate tissue (p. 31, 46-47; Example 8), administering a SV-NGEP polypeptide to a subject to generate an immune response (p. 39), administering a SV-NGEP polypeptide to induce a CTL response (p. 40; Example 9). It is noted that the specification lacks working models demonstrating all of these utilities.

Following the requirements of the Utility Guidelines, (<http://www.uspto.gov/web/offices/pac/utility/utilityguide.pdf>), "substantial utility" is a utility that defines "real world use", wherein utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In the instant case, the asserted "real world" utilities of the claimed polypeptides are producing an antibody for the detection of the claimed polypeptide in order to detect prostate tissue, administering a SV-NGEP polypeptide to a subject to generate an immune response, administering a SV-NGEP polypeptide to induce a CTL response. These asserted "real world" utilities are not supported by the specification or the prior art. The specification neither identifies the functions of the proteins, nor demonstrates that the claimed proteins are associated with any diseases or would

predictably treat any disease.

The state of the prior art does not appear to teach the claimed polypeptides.

Utility must be in readily available form. One of skill in the art would recognize that novel biological molecules, such as the claimed polypeptides, lack an established utility and must undergo extensive experimentation to determine an appropriate specific, substantial, and credible utility. It is possible that, after further characterization, the claimed polypeptides might be found to have patentable utility. This further characterization, however, is part of the act of the invention, and until it has been undertaken, Applicant's claimed invention is incomplete.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility.

The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where *specific* benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is

not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to polypeptides with undetermined function or biological significance. Until a specific real world utility is attributed to the claimed polypeptides, the claimed invention is incomplete. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed polypeptides. Because the claimed invention is not supported by a specific and substantial utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 26-30, 39, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know *how to use* the claimed invention.

6. Claims 6, 8-11 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

The claims are drawn to an isolated nucleic acid sequence encoding the polypeptide of claim 1, wherein the polypeptide of claim 1 comprises: (1) an amino acid sequence **at least 90% homologous to SEQ ID NO:1**; or (2) **at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule** (claim 6, 8-11), and a pharmaceutical composition comprising a therapeutically effective amount of the polynucleotide of claim 6 (claim 40).

The specification discloses SV-NGEP sequence SEQ ID NO:2 which was detected as a gene uniquely expressed in prostate tissue (Fig. 3; Examples 2 and 3). The specification does not disclose any other nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule as broadly encompassed in the claims.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a recitation of

"an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule". Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that " [a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name', of the claimed subject matter sufficient to distinguish it from other materials. " Id. At 1567, 43 USPQ2d at 1405. The court also stated that:

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description nucleic acids that

encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule, per Lilly by structurally describing representative nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not directly describe nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule useful in the claimed invention in a manner that satisfies either the Lilly or Enzo standards. Although the specification discloses SEQ ID NO:2 which is predicted to encode SEQ ID NO:1, this does not provide a description of the broadly claimed nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated

polypeptide is eight to ten amino acids in length and binds a MHC molecule that would satisfy the standard set out in Enzo because the specification provides no functional characteristics coupled to structural features.

Further, the specification also fails to describe nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule by the test set out in Lilly because the specification describes only SEQ ID NO:2. Therefore it necessarily fails to describe a representative number of such species.

Thus, the specification does not provide an adequate written description of a nucleic acids that encode an amino acid sequence at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule that is required to practice the claimed invention.

7. Claims 6 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **an isolated nucleic acid sequence encoding the polypeptide SEQ ID NO:1**, does not reasonably provide enablement for a polynucleotide encoding (1) an amino acid sequence at least 90% homologous to SEQ ID NO:1; or (2) at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the isolated polypeptide is eight to ten amino acids in length and

binds a MHC molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to an isolated nucleic acid sequence encoding the polypeptide of claim 1, wherein the polypeptide of claim 1 comprises: (1) an amino acid sequence **at least 90% homologous to SEQ ID NO:1**; or (2) **at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1, wherein the**

isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule; or (3) an amino acid sequence set forth as SEQ ID NO:1 (claims 6, 8-11).

The specification discloses polynucleotide SEQ ID NO:2, SV-NGEP, was found to be uniquely expressed in prostate tissue and prostate cancer tissue but not in other normal tissues (Example 2). The specification discloses methods of detecting SEQ ID NO:2 to detect SV-NGEP expressing prostate cells in samples (p. 46, lines 30-33; p. 48, lines 10-30; Example 2).

One cannot extrapolate the disclosure of the specification to the enablement of the claims because the specification does not provide guidance or examples for making and using polynucleotide that would encode a polypeptide at least 90% homologous to SEQ ID NO:1, or an amino acid sequence set forth as SEQ ID NO:1 that would function as contemplated in the specification (see p. 31, 46-47; Example 8; p. 39; p. 40; Example 9), or a polynucleotide encoding a polypeptide that would function to bind an MHC molecule. The specification discloses only polynucleotide SEQ ID NO:2, which is uniquely expressed in prostate tissue and can be used as a marker for prostate tissue. A search of the art does not appear to enable the use of any other polynucleotides that encode the claimed polypeptides. Given the lack of utility and enablement for the claimed polypeptides as stated in the rejections of sections 4 and 5 above, one of skill in the art would not know how to use the polynucleotides encoding an amino acid sequences at least 90% homologous to SEQ ID NO:1; or at least eight consecutive amino acids of amino acids 157-933 of SEQ ID NO:1; wherein the isolated polypeptide is eight to ten amino acids in length and binds a MHC molecule; or an amino acid

sequence set forth as SEQ ID NO:1, other than polynucleotide SEQ ID NO:2.

The specification discloses that the claimed polynucleotides are novel (p. 5, lines 1-4). It is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Bera et al (PNAS, 2004, 101:3059-3064) teach SEQ ID NO:2 as a long form splice variant of "Novel Gene Expressed in Prostate" (NGEP-L) which is expressed only in prostate tissue (p. 3061, col. 2), however, a search of the art does not appear to enable the use of any other polynucleotides encoding the claimed polypeptides as contemplated by the specification. MPEP 2164.03 states: The "predictability or lack thereof" in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. If one skilled in the art can readily anticipate the effect of a change within the subject matter to which the claimed invention pertains, then there is predictability in the art. On the other hand, if one skilled in the art cannot

readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art. Accordingly, what is known in the art provides evidence as to the question of predictability. One of skill in the art would not know how to use the claimed polynucleotides, other than SEQ ID NO:2, to predictably function as claimed and contemplated.

Therefore, in view of the novel nature of the invention, what is unknown in the art because of the novel nature of the invention, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

8. Claims 10, 11, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed

invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a **host cell** transfected with the nucleic acid of claim 6 (claim 10), wherein the host cell is a mammalian cell (claim 11), a **pharmaceutical** composition comprising a therapeutically effective amount of the polynucleotide of claim 6 in a pharmaceutically acceptable carrier (claim 40).

It is noted that claims 10 and 11 reasonably read on the transfection of intact hosts and mammalian hosts with the claimed vector.

The specification contemplates administering SV-NGEP polynucleotides to elicit an immune response or immunize mammals (p. 42, lines 16-20; p. 43, lines 5-21) for therapeutic purposes such as therapy for prostate cancer (p. 44, lines 22-24; Example 7).

One cannot extrapolate the disclosure of the specification to the enablement of the claims because the specification does not provide guidance or examples for the claimed polynucleotides functioning as a pharmaceutical. One cannot extrapolate the

disclosure of the specification to the enablement of the claims because the specification does not provide guidance or examples for transfecting an intact mammal or host with the claimed polynucleotides wherein the polynucleotides would function in immunizing or therapy of mammals for cancer as contemplated by the specification. A search of the art does not appear to teach and enable the claimed polynucleotides to predictably function as a pharmaceutical or for the transfection of hosts for the purposes of immunization or therapy.

The specification discloses that the claimed polynucleotides are novel (p. 5, lines 1-4). It is noted that MPEP 2164.03 teaches that "the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability of the art. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The amount of guidance or direction refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as how to make and use the invention in order to be enabling."

Therefore, in view of the novel nature of the invention, what is unknown in the art because of the novel nature of the invention, the breadth of the claims, lack of guidance

in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Amendment of claim 10 to recite "an **isolated** host cell" would obviate this rejection of claims 10 and 11.

9. **Conclusion:** No claims are allowed. Claim 7 is objected to. Claims 1-6, 8-11, 26-30, 39, 40, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph but appear to be free of the prior art. The closest prior art appears to be WO 200175067-A2 (Drmanac et al, published 10/11/2001, filed 3/30/2001, IDS) (see sequence search result #4, Geneseq database) and WO 03/042370 (Pastan et al, published 5/22/2003, filed 11/13/2002, IDS). Drmanac et al teach a human diagnostic polypeptide sequence, ABG15488, with 75.5% homology to SEQ ID NO:1 of the instant application and includes SEQ ID NOs:4 and 5 predicted to be MHC binding peptides of SEQ ID NO:1 in the specification. Drmanac et al do not teach or suggest the claimed polypeptides or polynucleotides encoding polypeptides. Pastan et al teach a polypeptide and polynucleotide encoding "Novel Gene Expressed in Prostate" (NGEP), which is specifically expressed in prostate tissue, and wherein the protein sequence of NGEP (SEQ ID NO:1) has identical amino acids 1-155 with SEQ ID NO:1 of the instant application. Pastan et al does not teach or suggest the long form splice variant of NGEP, the claimed polynucleotides or polypeptides.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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